

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND)
COMPOUNDING PHARMACY, INC.)
PRODUCTS LIABILITY LITIGATION)**

MDL No. 2419

This Document Relates to:

Dkt. No. 1:13-md-2419 (RWZ)

**Wray v. Ameridose, LLC, et al.
1:13-cv-12737**

**STATE OF TENNESSEE’S MEMORANDUM OF LAW
IN SUPPORT OF TENN. CODE ANN. § 29-26-121(f)**

The State of Tennessee submits this Memorandum of Law in Support of Tenn. Code Ann. § 29-26-121(f). In the instant case, Plaintiffs assert that Tenn. Code Ann. § 29-26-121(f) is preempted by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). (Doc. 55, p. 7.) This Court granted the State of Tennessee’s motion for leave to file a response in support of the statute. (Doc. 58.)

ARGUMENT

HIPAA DOES NOT PREEMPT TENN. CODE ANN. § 29-26-121(f).

The United States Constitution “establishes a system of dual sovereignty between the States and the Federal Government.” *Gregory v. Ashcroft*, 501 U.S. 452, 457 (1991). The states “retain substantial sovereignty authority under our constitutional system.” *Id.* A court’s preemption analysis should begin “with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” *Altria Group, Inc. v. Good*, 555 U.S. 70, 77 (2008).

When enacting HIPAA, the federal legislature imposed a duty on the Secretary of Health and Human Services to publish rules and regulations pertaining to the privacy of protected health information. 42 U.S.C. §§ 1320a, 1320d–1320d-9. The regulations contain an express preemption clause: “A standard, requirement, or implementation specification adopted under this subchapter that is *contrary* to a provision of State law preempts the provision of State law.” 45 C.F.R. § 160.203 (emphasis added). “Contrary” means:

- (1) A covered entity would find it impossible to comply with both the State and federal requirements; or
- (2) The provision of State law stands as an obstacle to the accomplishment and execution of the full purpose and objectives of part C of title XI of the Act, section 264 of Public Law 104-191, or section 13402 of Public Law 111-5, as applicable.

Id. at § 160.202.

Plaintiffs acknowledge that the impossibility test is not at issue here. (Doc. 55, p. 9.) Their sole argument for preemption is that Tenn. Code Ann. § 29-26-121(f) stands as an obstacle to the accomplishment and execution of the full purpose and objectives of HIPAA. (Doc. 55, pp. 9-10.)

In conducting such a preemption inquiry, a court may exam “the regulation, including its history, the promulgating agency’s contemporaneous explanation of its objectives, and the agency’s current views of the regulation’s pre-emptive effect.” *Williamson v. Mazda Motor of America, Inc.*, 562 U.S. 323, 330 (2011). The Supreme Court has cautioned that “[i]mplied preemption analysis does not justify a ‘freewheeling judicial inquiry into whether a state statute is in tension with federal objectives’; such an endeavor ‘would undercut the principle that it is Congress rather than the courts that preempts state law.’” *Chamber of Commerce of U.S. v. Whiting*, 131 S.Ct. 1968, 1985 (2011) (quoting *Gade v. National Solid Wastes Mgt. Assn.*, 505 U.S. 88, 111 (1992)). The Supreme Court has stated: “Our precedents ‘establish that a high

threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act.” *Id.*

A. Both HIPAA and Tenn. Code Ann. § 29-26-121(f) Allow for the Disclosure of Protected Health Information in a Judicial Proceeding.

By enacting HIPAA, Congress sought to improve “the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.” Pub. L. No. 104-191, § 261, 1996 HR 3101 (1996). Congress also recognized the need for standards pertaining to the privacy of health information and mandated that the Secretary of Health and Human Services promulgate final regulations containing such standards if Congress did not. *Id.* at § 264. After Congress did not act, the Department of Health and Human Services (“Department”) promulgated the regulations, the Standards for the Privacy of Individually Identifiable Health Information, 45 C.F.R. §§ 160, 164, known as the “Privacy Rule.”

The Privacy Rule requires a covered entity¹ to use or disclose protected health information pursuant to its provisions. 45 C.F.R. § 164.502. “Protected health information” means, in relevant part, individually identifiable health information that is transmitted by electronic media, maintained in electronic media, or transmitted or maintained in any other form or medium. *Id.* § 160.103. “Health information” is defined to include information “oral or recorded in any form or medium.” *Id.* As a general rule, a covered entity must make reasonable efforts to use or disclose the minimum necessary to accomplish the intended purpose of the use, disclosure, or request. *Id.* § 164.202(b)(1).

When publishing the Privacy Rule, the Department stated:

¹ A covered entity is defined as a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form. 45 C.F.R. § 160.103.

This regulation has three major purposes: (1) To protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information; (2) to improve the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care; and (3) to improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals.

65 Fed. Reg. 82462–01, 82463 (Dec. 28, 2000). The Department sought to balance privacy interests with the social goals of disclosure. *Id.* at 82471.

The Privacy Rule provides for the use or disclosure of protected health information without a patient’s consent in a variety of circumstances, including for a judicial or administrative proceeding. 45 C.F.R. § 164.512. In the course of a judicial proceeding, a covered entity may disclose protected health information in response to an order of a court. *Id.* § 164.512(e)(1). It may make the same disclosure in response to lawful process that is not accompanied by a court order so long as either (1) reasonable efforts have been made to provide notice to the patient, or (2) reasonable efforts have been made to secure a qualified protective order that prohibits disclosure for any purpose other than the litigation and requires the return or destruction of information at the end of litigation. *Id.* §§ 164.512(e)(1)(ii)–(v).

In promulgating these regulations, the Department made clear that HIPAA was “not intended to disrupt the current practice whereby an individual who is a party to a proceeding and has put his or her medical condition at issue will not prevail without consenting to the production of his or her protected health information.” 65 Fed. Reg. 82462–01, at 82530. The agency also discussed the interplay between the “minimum necessary” standard and a disclosure in a judicial proceeding:

In complying with the request, however, the covered entity must make reasonable efforts not to disclose more information than is requested. For example, a covered entity may not provide a party free access to its medical records under the theory that the party can identify the information necessary for the request. In some instances, it may be appropriate for a covered entity, presented with a relatively broad discovery request, to permit access to a relatively large amount of information in order for a party to identify the relevant information. This is permissible as long as the covered entity makes reasonable efforts to circumscribe the access as appropriate.

Id.

Tenn. Code Ann. § 29-26-121(f) likewise allows for the disclosure of protected health information in the course of a judicial proceeding while also protecting a patient's privacy. The statute provides:

(f)(1) Upon the filing of any "healthcare liability action," as defined in § 29-26-101, the named defendant or defendants may petition the court for a qualified protective order allowing the defendant or defendants and their attorneys the right to obtain protected health information during interviews, outside the presence of claimant or claimant's counsel, with the relevant patient's treating "healthcare providers," as defined by § 29-26-101. Such petition shall be granted under the following conditions:

(A) The petition must identify the treating healthcare provider or providers for whom the defendant or defendants seek a qualified protective order to conduct an interview;

(B) The claimant may file an objection seeking to limit or prohibit the defendant or defendants or the defendant's or defendants' counsel from conducting the interviews, which may be granted only upon good cause shown that a treating healthcare provider does not possess relevant information as defined by the Tennessee Rules of Civil Procedure; and

(C)(i) The qualified protective order shall expressly limit the dissemination of any protected health information to the litigation pending before the court and require the defendant or defendants who conducted the interview to return to the healthcare provider or destroy any protected health information

obtained in the course of any such interview, including all copies, at the end of the litigation;

(ii) The qualified protective order shall expressly provide that participation in any such interview by a treating healthcare provider is voluntary.

(2) Any healthcare provider's disclosure of relevant information in response to a court order under this section, including, but not limited to, protected health information, opinions as to the standard of care of any defendant, compliance with or breach of the standard, and causation of the alleged injury, shall be deemed a permissible disclosure under Tennessee law.

(3) Nothing in this part shall be construed as restricting in any way the right of a defendant or defendant's counsel from conducting interviews outside the presence of claimant or claimant's counsel with the defendant's own present or former employees, partners, or owners concerning a healthcare liability action.

Tenn. Code Ann. § 29-26-121(f).

Only a defendant in a health care liability action may utilize its provisions. *Id.* § (f)(1). The defendant must petition the court, argue any relevancy issues raised by plaintiff, and obtain a qualified protective order from the court before he or she may seek an *ex parte* interviews with plaintiff's healthcare providers. *Id.*

B. Tenn. Code Ann. § 29-26-121(f) Does Not Conflict with HIPAA and is Not an Obstacle to the Accomplishment of HIPAA's Objectives.

The United States District Court for the Western District of Tennessee has concluded that HIPAA does not preempt Tenn. Code Ann. § 29-26-121(f). In *Lovelace v. Pediatric Anesthesiologists, P.A.*, No. 2:13-cv-02289-JPM-dkv (W.D. Tenn. Feb. 5, 2014) (copy attached), the plaintiffs argued that subsection (f) "lowers HIPAA's privacy standards" and thus is preempted. (Order Granting Motion of Defendants for Qualified Protective Order at 8.) The district court concluded that "Tenn. Code Ann. § 29-26-121(f) is not 'contrary' to HIPAA. It is possible for healthcare providers to comply with both HIPAA and Tenn. Code Ann. § 29-26-121(f)

simultaneously, and Tenn. Code Ann. § 29-26-121(f) does not stand as an obstacle to the accomplishments of HIPAA.” *Id.* at 15.² The district court further stated:

Both HIPAA and Tenn. Code Ann. § 29-26-121(f) seek to protect the privacy of individual health information. Both permit the disclosure of protected health information in a judicial proceeding pursuant to a qualified protective order entered by the court. Both require the same safeguards and limitations on dissemination and use of the information and destruction of the information at the end of the proceeding in the qualified protective order for the protection of the privacy of an individual’s health care information. Both are limited to the discovery of relevant information. Both permit *ex parte* communications between defense counsel and a Plaintiffs’ treating physician.

Id. at 15-16. In addition, “[t]he ‘good cause’ and relevancy standards in Tenn. Code Ann. § 29-26-121(f) are consistent with the standards for discovery and the issuance of protective orders under the Federal Rules of Civil Procedure, which would apply to HIPAA.” *Id.* at 16.

Tennessee Code Annotated § 29-26-121(f) does not stand as an obstacle to accomplishing the purposes and objectives of HIPAA. The disclosure of protected health information may not occur unless a defendant obtains a qualified protective order from a court, so subsection (f) authorizes disclosure expressly contemplated by HIPAA. Its provisions apply only to persons who have voluntarily made their health an issue by filing a healthcare liability lawsuit. *Id.* And subsection (f) goes further to protect that patient’s privacy. Protections for a patient’s privacy are contained expressly within the statute: disclosure is limited to the defendant(s) in the healthcare liability action and their attorneys; the claimant has an opportunity to object based on relevancy; the use and disclosure of any protected health information is limited to the litigation pending before

² The decision in *Lovelace* is consistent with that court’s previous conclusion that “the exceptions to HIPAA’s privacy rules allow defense counsel to conduct *ex parte* interviews with plaintiffs’ treating physicians after first securing, or attempting to secure, a qualified protective order consistent with the regulations.” *Wade v. Vabnick-Wener*, 922 F.Supp.2d 679, 690 (W.D. Tenn. July 2, 2010).

the court; and any information received must be returned or destroyed at the end of litigation. *Id.* In addition, the qualified protective order must expressly provide that participation is voluntary. *Id.* § (f)(1)(C)(ii).

Plaintiffs fail to meet their high burden to show that Tenn. Code Ann. § 29-26-121(f) is preempted by HIPAA. First, Plaintiffs argue that HIPAA requires a covered entity to disclose only the minimum necessary to comply with a request while Tenn. Code Ann. § 29-26-121(f)(2) permits a physician to disclose any information. (Doc. 55, p. 11.) But Tenn. Code Ann. § 29-26-121(f) seeks to limit the information that may be disclosed in an *ex parte* interview sought under its terms. It requires the defendant to identify relevant healthcare providers in its petition and allows the plaintiff the opportunity to seek to limit or prohibit an interview based on relevancy. Tenn. Code Ann. § 29-26-121(f)(1). While the statute provides that disclosure in response to a court order under this section is a “permissible disclosure under Tennessee law,”³ it does not remove a healthcare provider’s obligation to abide by HIPAA’s “minimum necessary” standard when making any disclosure.

Second, Plaintiffs claim that HIPAA methods place the burden on the requestor to show that an *ex parte* interview is necessary. (Doc. 55, pp. 11-12.) Plaintiffs do not cite to a specific provision of HIPAA or other authority to support their interpretation of HIPAA and its methods. *See id.* In fact, the Privacy Rule states that disclosure may occur in the course of any judicial proceeding in response to and in accordance with an order of a court. 45 C.F.R. § 164.512(e)(1). It does not specify or control by what means a court order may be obtained. *See id.* The Privacy Rule also provides a method by which disclosure may occur in response to a subpoena if the person

³ Subsection (f)(2) was amended in 2014 to clarify that “disclosure of relevant information in response to a court order under this section . . . shall be deemed a permissible disclosure under Tennessee Law.” Tenn. Code Ann. § 29-26-121(f)(2).

requesting protected health information gives notice to the subject individual and time for them to raise objections. *Id.* at § 164.512(e)(1)(ii)(A). Thus, Tenn. Code Ann. § 29-26-121(f) provides similar methods to those of HIPAA with regard to obtaining disclosure in the course of a judicial proceeding.

Third, Plaintiffs argue that Tenn. Code Ann. § 29-26-121(f) is an obstacle to the objectives of HIPAA due to the risk that irrelevant information could be disclosed in an *ex parte* interview. (Doc. 55, pp. 12-14.) But, as discussed above, even the Department recognized that irrelevant information could be disclosed under its regulations in a judicial proceeding and stated: “[i]n some instances, it may be appropriate for a covered entity, presented with a relatively broad discovery request, to permit access to a relatively large amount of information in order for a party to identify the relevant information. This is permissible as long as the covered entity makes reasonable efforts to circumscribe the access as appropriate.” 65 Fed. Reg. 82462–01, 82530 (Dec. 28, 2000). And as discussed above, Tennessee Code Annotated § 29-26-121(f) and the Privacy Rule contain similar privacy protections. A court should not seek out conflicts “between state and federal regulation where none clearly exists.” *Exxon Corp. v. Gov. of Maryland*, 437 U.S. 117, 130 (1978).

Finally, Plaintiffs cite to *Proctor v. Messina*, 320 S.W.3d 145, 150 (Mo. 2010), as an example of a court that has strictly construed the Privacy Rule to find that it does not permit *ex parte* interviews. (Doc. 55, pp. 13.) *Proctor* is distinguishable from the instant case because Missouri had not enacted a statute that permitted *ex parte* interviews. 320 S.W.3d at 157. In fact, the court’s analysis in *Proctor* supports that Tenn. Code Ann. § 29-26-121(f) is not contrary to HIPAA. The court stated that HIPAA “does not itself authorize any additional process or procedure for obtaining a court order, subpoena, or other lawful process; that is left to the rules in the individual states.” *Id.* at 156-157. “If either the state law or HIPAA (or both) is permissive,

that is, at least one of the statutes allows a particular action but does not compel it, then the statutes are not contrary under the impossible and obstacle tests.” *Id.* at 158, fn.10. The court further explained:

For example, if a state law permits *ex parte* interviews and HIPAA allows them if certain procedures are followed, then a covered entity could be in compliance with both statutes by either not engaging in *ex parte* discussions at all (since neither statute compels them), or by engaging in them after satisfying HIPAA’s procedural requirements. Since there are no impediments to complying with both HIPAA and the state law, the statutes are not contrary under the impossibility test, and the state law is not an obstacle to HIPAA compliance.

Id. Tennessee Code Annotated § 29-26-121(f) specifically authorizes *ex parte* interviews, provides that they are voluntary on part of the provider, requires a petition process through which an order may be obtained, and gives the court discretion over whether to enter an order based on relevancy. Therefore, under the *Proctor* analysis, Tenn. Code Ann. § 29-26-121(f) is not preempted by HIPAA.

CONCLUSION

For the reasons stated above, this Court should hold that HIPAA does not preempt Tenn. Code Ann. § 29-26-121(f).

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CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the foregoing document to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Date: February 12, 2016

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